

Individual Safety Report



3251994-1-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil

 Consumer Healthcare
 McNeil Consumer Healthcare
 Fort Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

Page ____ of ____

A. Patient information				C. Suspect medication(s)			
1. Patient identifier unknown In confidence	2. Age at time of event: or adult Date of birth:	3. Sex () female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 <u>TYLENOL Analgesic Unknown</u> #2 _____			
B. Adverse event or product problem				2. Dose, frequency & route used #1 <u>unknown dose, po</u> #2 _____			
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 <u>unknown</u> #2 _____			
2. Outcomes attributed to adverse event (check all that apply) () death (mo/day/yr) () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:				4. Diagnosis for use (indication) #1 <u>unknown</u> #2 _____			
3. Date of event (mo/day/yr) <u>unknown</u>				6. Lot # (if known) #1 <u>Unknown</u> #2 _____		7. Exp. date (if known) #1 <u>Unknown</u> #2 _____	
4. Date of this report (mo/day/yr) <u>04/27/99</u>				5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
5. Describe event or problem Nurse's written report of HEPATIC FAILURE (liver failure) allegedly associated with one of our TYLENOL ® acetaminophen products in a male patient. According to nurse, a young man was drinking alcohol at a party and the following morning he took an unspecified amount of TYLENOL . Subsequently, he was hospitalized in the Intensive Care for several days with a diagnosis of liver failure. No further information was provided.				8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
6. Relevant tests/laboratory data, including dates unknown DSS MAY 04 1999 ADVERSE EVENT REPORTING SYSTEM				9. NDC # - for product problems only (if known) - -			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) drank alcohol at a party the night before taking TYLENOL MAY 13 1999				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
G. All manufacturers				1. Contact office - name/address (& mailing site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034			
2. Phone number 215-273-7820				3. Report source (check all that apply) () foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:			
4. Date received by manufacturer (mo/day/yr) <u>04/20/99</u>				5. (A) NDA # <u>19-872</u> IND # PLA # pre-1938 () Yes OTC product (X) Yes			
6. If IND, protocol #				7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #			
8. Adverse event term(s) LIVER FAILURE				9. Mfr. report number 1165439A			
E. Initial reporter							
1. Name, address & phone # _____, RN, BSN _____, Road _____							
2. Health professional? (X) Yes () No		3. Occupation nurse		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			



Facsimile Form 3500A

Submission of a report does NOT constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.